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ANDREA Q. RYAN			EXAMINER	
SANOFI-AVENTIS U.S. LLC			CHONG, KIMBERLY	
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BRIDGEWATER, NJ 08807			PAPER NUMBER	
			1635	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/574,416

Applicant(s)

GRUENEBERG ET AL.

Examiner

KIMBERLY CHONG

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 9-15 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-32 is/are allowed.
- 6) ☒ Claim(s) 1, 3-6 and 9-11 is/are rejected.
- 7) ☒ Claim(s) 12-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 01/08/2009 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 03/17/2008 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 09/17/2008, claims 1, 3-6, 9-15 and 23-32 are pending and currently under examination.

Claims 23-32 are free of the prior art searched and made of record.

Claim Objections

Claims 12-15 are objected to as being dependent upon a rejected base claim and reciting non-elected subject matter, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and deleting non-elected subject matter.

Claim Rejections - 35 USC § 112 - withdrawn

Claims 1 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The rejection of claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 USC § 103 - maintained

The rejection of claims 1, 4-6 and 9-11 under 35 U.S.C. 103(a) as being unpatentable over Devroe et al. (BMC Biotechnology August 2002), Noonberg et al. (US Patent NO. 5,624,803) and Chang et al. (Current Gene Therapy, 2001, 1: 237-251) is maintained.

The rejection of claims 1, 4-6 and 9-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Verma et al. (US 2004/0234504), Noonberg et al. (US Patent NO. 5,624,803) and Chang et al. (Current Gene Therapy, 2001, 1: 237-251) is maintained for the reasons of record.

Applicant's arguments filed 01/08/2009 have been fully considered but they are not persuasive. Applicant argues the Examiner has not provided any evidence in support of the statement that the claimed U6 promoter and the U6 promoter are patentably indistinguishable. Applicant further argues Chang et al. teach the REV element is not necessary and therefore the claimed invention is clearly novel and nonobvious.

As stated in the previous Office action, the claimed U6 promoter and the U6 promoter taught by Noonberg et al. differ by one nucleotide and because Noonberg et al. teach the essential elements required for the U6 promoter to initiate transcription of an oligonucleotide insert (see at least column 13 and Figure 4B) which the claimed U6 promoter sequence has, the two promoters are patentably indistinguishable. Further Noonberg et al. teach U6 promoters mutations that are capable of initiating transcription of an oligonucleotide insert. Applicant has not provided any evidence that the prior art U6 promoter would not be capable of being used in the claimed retroviral vector nor why it would not have been obvious to use the U6 promoter taught by Noonberg et al. Therefore it would have been obvious to use U6 promoter taught by Noonberg et al.

Applicant's argument regarding Chang et al. is not persuasive. The paragraph cited by Applicant as proof that Chang et al. teach the rev element is not necessary is taken out of context. If read in its entirety, Chang et al. do in fact state the rev element is necessary for efficient transport to cells. Chang et al. teach that others in the art have tried to overcome this requirement when using lentiviral vectors but the vectors have diminished titers and some of the approaches to element this requirement is said

vectors is labor-intensive and inefficient. Therefore, Chang et al. does not teach that efficient expression from lentiviral vectors does not require the rev element and outlines the consequences of trying to eliminate this element.

Thus, the claimed invention would have been obvious to one of ordinary skill in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-

3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635